REMARKS

Claims 1 and 3 have been amended. Claims 30 and 31 have been canceled. Claims 4-7, 13-20 and 22-29 have been withdrawn from consideration as being directed to non-elected inventions. Thus, claims 1, 3, 8-10 and 21 are now presented for examination. No new matter has been added. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1, 3, 8, 10, 21, 30 and 31 as allegedly being indefinite based on recitation of "or a fragment thereof that inhibits trypanosome infection" and "the term "trypanolytically" active fragment in claims 1 and 3, respectively. Although Applicants do not agree with the rejection, claims 1 and 3 as amended no longer recite the terms considered to be indefinite by the Examiner.

In view the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-3, 8, 10, 21, 30 and 31 under 35 U.S.C. § 112, first paragraph, stating that "while being enabling for "an isolated polypeptide comprising SEQ ID NO: 1 (and the specific fragments recited in claim 3)" does not reasonably provide enablement for pharmaceutical compositions comprising a polypeptide having greater than 95% sequence identity to SEQ ID NO: 1 of any fragment thereof that inhibits any trypanosome infection, any composition comprising, or for any method of prevention or amelioration of infection by any species of Trypanosoma through the administration of the polypeptide comprising SEQ ID NO:1 or the fragments recited in claims 1 and 3. The Examiner also contended that the specification provided no written description of such variant polypeptides or fragments thereof.

Although Applicants believe that the currently pending claims are fully enabled and described by the specification as filed, claim 1 as amended no longer recites "...greater than 95% sequence identity or a fragment thereof," and instead recites "a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an isolated polypeptide comprising SEQ ID NO: 1" which was acknowledged by the Examiner to be enabled. Claim 3 as

amended is an independent claim that recites the polypeptides which were acknowledged by the Examiner to be enabled. Thus, claims 1-3 as amended fully comply with the enablement and written description requirements .

Applicants do not agree that the specification is not enabled for prevention, inhibition or amelioration of any infection caused by any species of Trypanosoma. The Office Action alleges that the specification provides neither *in vitro* nor *in vivo* results of treating or protecting against diseases caused by these organisms. However, the specification clearly enables a method of ameliorating and/or preventing a Trypanosoma infection in a mammal by administering a pharmaceutical composition comprising the isolated polypeptide of present claim 1, or a fragment thereof as recited in present claim 3. The Examples in the present specification at pages 19-21 demonstrate that the polypeptides recited in the present claims promote lysis of trypanosomes. One of ordinary skill in the art will appreciate that the lytic activity of these polypeptides will necessarily inhibit, prevent and/or cure trypanosome-mediated diseases since lysis of the causative agents will result in amelioration and/or the inability of these organisms to infect a mammal.

Courts have routinely held that when the art recognizes a correlation between *in vitro* assays and *in vivo* results, the specification need not provide *in vivo* data in order to be enabling. The Examiner bears the burden of proving that such a correlation does not exist. *See*, for example, *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); and M.P.E.P. § 2164.02.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicants submit that all claims are in condition for allowance. If any minor matters remain that could be resolved by teleconference, the Examiner is invited to contact the undersigned at the telephone number provided below. Please charge any additional fees, including any fees for extensions of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3/2/09

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